

Remarks:

Claims 1-3, 5-28, and 30-38 are pending in this application. The Office Action rejects all claims. Claims 1-3, 5-28, and 30-38 are first rejected as anticipated by U.S. Patent No. 5,755,773 to Evans et al. (Evans). Claims 1-3, 5-28, and 30-38 are further rejected as unpatentable based on United States Patent No. 6,017,363 to Hojeibane (Hoejeibane) in view of Evans. Applicants respectfully traverse these rejections and submit that the pending claims, as amended, should be allowed for the reasons set forth below.

35 U.S.C. § 102

Claims 1-3, 5-28, and 30-38 are rejected as being anticipated under 35 U.S.C. § 102(b) by Evans.

Evans discloses an "Endoluminal Prosthetic Bifurcation Shunt." Evans teaches a device that incorporates what it calls a "fallback procedure" by which an implanting surgeon can elect to seal off one of the device's branches by deploying a shunt (91 or 92) into that branch. Evans, col. 4, lines 4-7; col. 9 lines 18-50; Figs. 4A, 4B, and 7C. The surgeon then provides an alternative circulation route to the shunted artery by performing a bypass downstream of the shunt. Evans, col. 9, line 61 to col. 10, line 2; Fig. 7D. The disclosure of Evans is therefore directed to devices and methods for *eliminating* circulation to a branch. A sealing engagement between its components is in the context of "sealing off" the flow to one branch. Evans, col. 9, lines 29-33.

In marked contrast, applicants disclose and claim methods and devices for *delivering* circulation to each of the branches of a bifurcated device. Applicants' disclosure, page 3 lines 9-14 and page 8, lines 18-24. Applicants' independent claims 1, 25, 30, and 31, as amended, indicate that the leg portion of the device are open to permit flow through their length. In fact, the applicants' device takes advantage of this flow to enhance the sealing engagement between the two interlocked members. *Id.*, page 3, lines 15-16 and page 8, lines 24-27. This sealing can be further enhanced by, for example, incorporating an impingement area into the second member. *Id.*, page 3, lines 16-18 and page 8, lines 27-29.

Applicants respectfully submit that Evans fails to disclose an aperture at each leg portion of its device as claimed in applicants' amended claims 1, 25, 30, and 31. Therefore, Evans cannot anticipate these claims. Further, because dependent claims 2-3, 5-24, 26-28, and 32-

38 depend, directly or indirectly, from independent claims 1, 25, 30, and 31 Evans cannot anticipate these dependent claims. Applicants therefore respectfully submit that this rejection should be withdrawn.

35 U.S.C. § 103(a)

Claims 1-3, 5-28, and 30-38 are further rejected as unpatentable based on United States Patent No. 6,017,363 to Hojeibane (Hoejeibane) in view of Evans.

Hojeibane is relied upon in the Office Action for its disclosure of a bifurcated stent apparatus. Evans is relied upon in the Office Action for its disclosure of "a bifurcated stent including stent cover and seal ring." See Office Action of January 4, 2005 at page 3.

There is no need, and hence no suggestion, for either reference to adopt or be combined with the structure disclosed in the other reference. Hojeibane does not disclose a sealing relationship between modular members at all, because it only discloses an uncovered stent. Evans does not disclose overlapping engagement of trunk portions of a multi-component device. Specifically, there is no suggestion to combine (a) features of an interlocking stent used to relieve a vascular obstruction, as disclosed by Hojeibane, with (b) an endoluminal shunt used to isolate a vascular aneurysm, as discussed by Evans. Therefore, the applicants respectfully submit that a person of ordinary skill in the art would not be motivated to combine the references as suggested by the Examiner, and even if such a combination were made, the combination fails to teach the applicants' invention as claimed.

Claim 25 recites a modular endoluminal device comprising first and second members, in which the first member and second member are "adapted to interlock together such that [fluid flow] forces the second member against the first member in a sealing relationship." For the same reasons as discussed above, the cited references do not teach the claimed invention, as Evans teaches a stent-graft shunt member and Hojeibane does not teach a sealing relationship at all. Thus, there is no disclosure of fluid flow forcing interlocking members together in either reference, nor would fluid flow inherently provide an impingement force in the systems disclosed by either reference. The fluid flow would have essentially no impact on the uncovered stents disclosed in Hojeibane.

There must be objective motivation to support an obviousness rejection. *Ex parte Metcalf*, 67 USPQ2d 1633 (May 2, 2003). More specifically, the mere fact that teachings found in the prior art could be combined as proposed by an examiner does not make the combination

obvious "absent some teaching, suggestion or incentive supporting the combination." *Id.* at 1635 (citing *Carella v. Starlight Archery and Pro Line Co.*, 231 USPQ 644, 647 (Fed. Cir. 1986)). It is respectfully submitted that the Examiner has failed to identify any such teaching, suggestion, or incentive to support his proposed combination. Accordingly, it is respectfully submitted that claims 1, 25, 30 and 31, as amended, are patentable over the art of record. Likewise, it is respectfully submitted that claims 2, 3, 5-24, and 39 which depend from claim 1, claims 26-28 which depend from claim 25, and claims 32-38 which depend from claim 31 are also patentable over the art of record.

In regard to claim 23, the Office Action indicates that the claim as recited is obvious based on Hojeibane in light of Evans because the applicants have not disclosed how having the first opening with a greater open area than the second opening "solves any stated problem or is for any particular purpose." See Office Action of January 4, 2005 at page 3. Because of the sealing relationship claimed by the applicant, the interface between the members in the crotch region where the branching lumens join the main body may be of critical importance in some embodiments. In an embodiment in which the second opening has the same open area as the first opening (particularly if the first and second members are identical), the openings may overlap at the crotch region, potentially creating a poor seal where the openings come together, which may be aggravated if fluid flow forces the second member too far down into the first opening. In embodiments in which the second opening is smaller than the first opening, the entire periphery of the first opening, particularly the portion in the crotch region, may be able to contact graft material of the second member, creating a better seal. Also, the smaller opening in the second member may provide a greater fluid impingement area for driving the second member into the sealing relationship with the first member. The advantages of embodiments having the features recited in claim 23 are unique to the claimed invention of providing a sealing relationship in the trunk region of the interlocking members, further emphasizing the non-obviousness of the invention over the cited references.

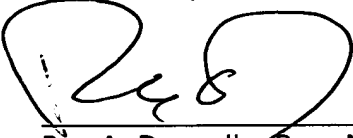
To the extent that the Office Action raises the issue that the specification fails to state how the difference in the opening sizes solves any stated problem, the applicants respectfully submit that neither an applicant's arguments nor evidence traversing an obviousness rejection need be contained within the specification. The PTO may not disregard the evidence and arguments made by an applicant in response to an obviousness rejection on the grounds that the advantage is not disclosed in the application. *In re Chu*, 36 USPQ2d 1089, 1095 (Fed. Cir. 1995) (reversing PTO's rejection of improvement as "merely an obvious design choice"). To

require evidence and argument that something is not merely a matter of design choice in the specification would be to require patent applicants "to divine the rejections the PTO will proffer when patent applications are filed." *Id.* at 1094. Accordingly, it is respectfully submitted that claim 23 is patentable over the prior art of record.

Summary

In view of the arguments set forth above, the applicants respectfully submit that claims 1-3, 5-28, and 30-38 are in condition for allowance. Early and favorable notification to this effect is respectfully requested.

Respectfully submitted,



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